

caBIG

Clinical Trials Management Workspace
Adopter

CASE Comprehensive Cancer Center

Bob Lanese

Programmer / Analyst

Clinical Trials Unit

robert.m.lanese@case.edu

Data Provided

- Demographic, Clinical, Laboratory, and Radiology data covering over 5000 patients and 450 protocols
- Phases 1, 1/2, 2, 3
- Therapeutic and Non-therapeutic studies

Envisioned Tools

- CDUS and Theradex electronic reporting
- SAE electronic reporting
- Elimination of double data entry by using a one-pass process from the initial data

Evaluation of Tools

Clinical and data adopter teams

- Clinical Process: clinical trials administrator, clinical trials research nurses
- Data Process: database administration, data managers
- Processes will overlap through feedback loops

System Integration

- Adopted on a development environment proceeding to production environment
- Hardware based on Intel chipset
- OS based on Microsoft, (Windows 2000)

End User Testing

- Interaction between Programmers, Data Manager, and Clinical Trials Administrator based on:
 - Application testing
 - Data validation testing

Software Validation

- Define a precise scope with a set of functional requirements before development
- Develop rule-based testing methodologies based on industrial testing standards as well as specific application testing standards

Interaction

- Designation of a team from both development and adoption sides and development of appropriate workflow processes
- Web-based project workspace linked to developers and adopters to disseminate information.
- Web-based discussion forum
- Conference calls, meetings, technical support
- Traditional methods